K113218

JAN 2 6 2012

4.0 510(k) Summary

Sponsor:	Pioneer Surgical Technology 375 River Park Circle Marquette, MI 49855 (906) 225-5861 Contact: Sarah McIntyre or Emily Downs Prepared: October 28, 2011
Device Name:	Pioneer Release Laminoplasty Plating System
Classification:	Class II; NQW/ 888.3050 – Spinal interlaminal fixation orthosis Panel Code: 87
Predicate Devices:	K091994 DePuy Spine, Inc. Mountaineer Laminoplasty System (SE 1/7/10) K050082 Medtronic CENTERPIECE Plate Fixation System (SE 6/6/05)
Description:	The Pioneer Release Laminoplasty Plating System consists of implantable plates and screws that will act as a buttress to maintain decompression after a laminoplasty procedure. The system also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.
Intended Use:	The Pioneer Release Laminoplasty Plating System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The Pioneer Release Laminoplasty Plating System is used to hold the graft material in place in order to prevent the graft material from expulsion, or impinging the spinal cord.
Material:	The Pioneer Release Laminoplasty Plating System components are manufactured from biocompatible, implant grade ASTM F136 titanium alloy.
Performance Data:	Static and fatigue four point bend standard testing per recognized ASTM F2193 and axial screw pull-out per ASTM F543 standards were performed to establish substantial equivalence. The test results demonstrate that the Pioneer Release Laminoplasty Plating System functioned as intended and performed in a manner substantially equivalent to that of a predicate system.
Performance and SE Determination:	Equivalence for the Pioneer Release Laminoplasty Plating System is based on similarities of intended use, design, and physical characteristics when compared to predicate devices. Therefore, Pioneer Surgical Technology believes that there is sufficient evidence to conclude that the Pioneer Release Laminoplasty Plating System is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 2 6 2012

Pioneer Surgical Technology, Inc.
% Ms. Sarah McIntyre
375 River Park Circle
Marquette, Michigan 49855

Re: K113218
Trade/Device Name: Pioneer Release Laminoplasty Plating System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: NQW
Dated: October 28, 2011
Received: November 01, 2011

Dear Ms. McIntyre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Peter Pitts

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.0 Indications for Use Statement

510(k) Number (if known): K113218

Device Name: Pioneer Release Laminoplasty Plating System

Indications: The Pioneer Release Laminoplasty Plating System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The Pioneer Release Laminoplasty Plating System is used to hold the graft material in place in order to prevent the graft material from expulsion, or impinging the spinal cord.

Prescription Use √ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113218